BOSTON MEDICAL CENTER HEALTHNet PLAN

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Pharmacy Policy

Genotropin®

Policy Number: 9.325
Version Number: 1
Version Effective Date: 1/1/2021

Product Applicability	☐ **All Plan[+] Products**
Well Sense Health Plan ☐ New Hampshire Medicaid	**Boston Medical Center HealthNet Plan** ☐ MassHealth ACO ☐ MassHealth MCO ☒ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- **Genotropin®**

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications unless otherwise excluded.
Exclusion Criteria	None
Required Medical Information	Diagnosis of: 1. Pediatric Growth Hormone deficiency; ***AND*** a. A subnormal growth velocity (age or pubertal status specific growth rate at less than the 10th percentile) or 2 standard deviation below mean; ***AND*** b. A subnormal GH response to a provocative stimulation test (2 tests) [a maximum GH

[+] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

level of < 10ng/ml ***OR***

2. Panhypopituitarism***; AND***

    a. There are deficiencies in growth hormone and at least one other pituitary hormone (TSH, ACTH, LH, FSH or AVP/ADH) ***OR***

3. Pediatric Chronic Renal Insufficiency***; AND***

    a. Conditions such as anemia, active malignancies, renal osteodystrophy, metabolic acidosis, malnutrition or fluid and electrolyte imbalance have been ruled out; ***AND***

    b. Evidence of growth impairment (the mean Z-score for growth velocity <-2 or mean Z-score for height based on age and gender <-1.88). ***OR***

4. Turner,Noonan or Prader -Willi Syndrome Syndrome***; AND***

    a. Height remains below 2 standard deviation below the mean ***OR***

5. Small for gestational age ***; AND***

    a. Height remains below 2 standard deviation below the mean at 2 years of age ***OR***.

6. Cachexia associated with AIDS***; AND***

    a. A failure of at least one other intervention addressing malnutrition. ***OR***

7. Adult growth hormone deficiency***; AND***

    a. Severe GH deficiency confirmed by a peak GH response of < 5 ng/mL during insulin tolerance tests (ITTs) or confirmed via alternative tests when ITTs are contraindicated: growth-hormone releasing hormone-arginine or glucagon stimulation (2 tests required); ***OR***

    b. GHD in childhood due to structural lesions with multiple hormone deficiencies or those with proven genetic causes AND low IGF-1 levels after at least 1 month off of GH therapy; ***OR***

    c. History of idiopathic childhood GHD with documentation of at least 1 subnormal provocative stimulation test after age 18; ***OR***

    d. A diagnosis of panhypopituitarism AND low serum IGF-I level. ***OR***

8. Short bowel syndrome***; AND***

    a. Short bowel syndrome management has been dependent on specialized nutritional support

Age Restrictions	None
Prescriber Restriction	The prescriber is a specialist appropriate to the disease state being treated (endocrinologist, nephrologist, etc)
Coverage Duration	Initial: Short bowel syndrome- 30 days Panhypopituitarism- lifetime approval All other diagnoses- 12 months Reauthorization: 12 months
Quantity Limit	None
Other criteria	Reauthorization: 1. For Pediatric, attestation of a growth rate > 2.5cm/yr (post-pubertal growth) or > 4.5cm/yr (pre-pubertal growth); ***OR*** 2. For adults, attestation of clinical benefit (increase in lean body mass/decreased fat mass, increase in IGF-1, or IGFBP-3, or an increase in exercise capacity).

Clinical Background Information and References

1. Evaluation and treatment of adult growth hormone deficiency: An endocrine society clinical practice guideline. J Clin Endocrinol Metab. 2011 Jun;96(6):1587-609.

2. American association of clinical endocrinologists medical guidelines for clinical practice for growth hormone use in adults and children – 2003 update. Endocrine practice; Vol 9 (1), Jan/Feb 2003.

3. Somatropin. In DrugDex® System (internet database). Version 5.1, Greenwood Village, Colo. Thomson Micromedex. Accessed June 2007.

4. Mecasermin. In DrugDex® System (internet database). Version 5.1, Greenwood Village, Colo. Thomson Micromedex. Accessed June 2007.

5. Waknine, Yael. FDA safety changes: Duetact®, Norditropin®, Nutropin®, Nutropin AQ®, Tev-Tropin®. Medscape Medical News. May 2007. Available from: http://www.medscape.com/viewarticle/555924.

6. Tonshoff, B. Growth hormone treatment in children with chronic kidney disease and post renal transplantation. UptoDate® Accessed June 2014.

7. Tev-Tropin® (package insert). Horsham (PA): Teva; Nov 2013.

8. Norditropin (package insert). Novo Nordisc. Plainsboro, NJ. Revised Jan 2015. Accessesd Jun 2015.

9. Lee PA, Chernausek SD, Hokken-Koelega ACS, Czernichow P. International small for gestation age advisory board consensus development conference statement: management of short children born small for gestational age, April 24-October 1, 2001. Pediatrics. 2003;111:1253-1261.

10. Nutropin [package insert]. South San Francisco, CA: Genentech; April 2012.

11. Nutropin AQ [package insert]. South San Francisco, CA: Genentech; March 2014.
12. Omnitrope (somatropin) [prescribing information]. Princeton, NY: Sandoz; August 2014.
13. Saizen [package insert]. Rockland, MA: Serono, Inc; June 2014.
14. Serostim [package insert]. Rockland, MA: Serono, Inc; April 2012.
15. Zomacton (somatropin) [prescribing information]. Parsippany, NJ: Ferring Pharmaceuticals; February 2016
16. Zorbtive [package insert]. Rockland, MA: Serono, Inc; January 2012.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	9.125 Genotropin Policy retired, new policy created	1/1/2021	P&T Committee

Next Review Date

2021

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the

medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.